AUG 2 8 2002

K022191
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TENOR™ Spinal System
510(k) Summary
August 2002

I. **Company:** **Medtronic Sofamor Danek USA**
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133

II. **Proposed Proprietary Trade Name: TENOR™ Spinal System**

III. **Classification Name: Orthosis, Spondylolisthesis Spinal Fixation (per 21 CFR Section 888.3070)**

IV. **Product Description**

The TENOR™ Spinal System is a spinal device intended to provide temporary, bilateral stabilization and augment the development of a solid spinal fusion. The system comprises a variety of shapes and sizes of clamps, cross connectors, nuts, and screws made of medical grade titanium alloy or stainless steel. The TENOR™ Spinal System is used in conjunction with GDLH™ 5.5mm rods, TSRH® hooks and connectors, TSRH® Low Profile CROSSLINK® plates, CD HORIZON(Low Profile MULTI-SPAN™ CROSSLINK® plates and/or MULTI AXIAL Low Profile MULTI-SPAN™ CROSSLINK® plates for attachment to the posterior thoracic and lumbar spine. These components are assembled to fit the patient's specific anatomic needs.

The purpose of this submission is to include additional screws to the system.

V. **Indications**

The TENOR™ Spinal System, when used for pedicle screw fixation, is intended only for patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar – first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine (levels of pedicle screw fixation may be from L3 to sacrum); and/or (d) who are having the device removed after the development of a solid fusion mass.

TENOR™ Plates are intended for the L5-S1 pedicle screw indication described above only.

The TENOR™ Spinal System, when used as a non-pedicle screw fixation system, is intended for the following indications: 1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), 2) pseudarthrosis, 3) stenosis, 4) spondylolisthesis, 5) spinal deformities: scoliosis, kyphosis, lordosis, 6) fracture, 7) unsuccessful previous attempts at spinal fusion, and/or 8) tumor resection. When used for posterior non-pedicle screw fixation, the TENOR™ Spinal System is intended for thoracic, lumbar, and sacral (T1-Sacrum) fixation only.

VI. **Substantial Equivalence**

Documentation was provided that demonstrated the TENOR™ Spinal System to be substantially equivalent to itself.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 8 2002

Mr. Richard W. Treharne, Ph.D.
Senior Vice President, Regulatory Affairs
Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K022191
Trade/Device Name: TENOR® Spinal System
Regulation Number: 21 CFR §888.3050 and §888.3070
Regulation Name: Spinal interlaminal fixation orthosis and Pedicle screw spinal system
Regulatory Class: Class II
Product Code: KWP and MNH
Dated: July 3, 2002
Received: July 5, 2002

Dear Dr. Treharne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K022191

Device Name: TENOR™ Spinal System

Indications for Use:

The TENOR™ Spinal System, when used for pedicle screw fixation, is intended only for patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar – first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine (levels of pedicle screw fixation may be from L3 to sacrum); and/or (d) who are having the device removed after the development of a solid fusion mass.

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(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Evaluation (ODE)

Prescription Use ✓ **OR** **Over-the-counter Use** _____
(Per 21 CFR 801.109)
(Optional 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022191/00047